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IN THE UNITED STATES DISTRICT COURT

DISTRICT OF UTAH, CENTRAL DIVISION

KLEIN-BECKER usa, LLC, a Utah limited liability company,

Plaintiff,

vs.

ALLERGAN, INC., a Delaware corporation, and MEDIACOM WORLDWIDE, INC., a Delaware corporation,

Defendants.

ALLERGAN, INC., a Delaware corporation,

Counterclaimant,

KLEIN-BECKER usa, LLC, a Utah limited liability company,

Counter-Defendant.

DEFENDANT ALLERGAN, INC.'S REPLY IN SUPPORT OF MOTION TO DISMISS THE FIRST, SECOND AND THIRD CAUSES OF ACTION IN PLAINTIFF'S SECOND AMENDED COMPLAINT

Case No.: 2:03CV00514 DB

Honorable Dee Benson

Magistrate Brooke C. Wells

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Defendant and counterclaimant Allergan, Inc. ("Allergan") submits this Memorandum in Reply to its Motion to Dismiss plaintiff and counterdefendant Klein-Becker usa, LLC's ("Klein-Becker") First, Second, and Third Causes of Action in its Second Amended Complaint ("SAC").

I. INTRODUCTION

Klein-Becker's opposition fails to rebut any of Allergan's arguments demonstrating that the first three claims in Klein-Becker's SAC must be dismissed for failure to state a claim. With regard to its trademark cancellation allegations, Klein-Becker fails to rebut that the "use in commerce" prong under the Lanham Act is satisfied by shipments of drugs for use in clinical trials prior to U.S. Food & Drug Administration ("FDA") approval of the drug for any particular indication. The SAC does not allege that Allergan did not ship BOTOX® product for clinical trials before obtaining FDA approval, and thus fails to allege facts that could show Allergan's declaration of use was false.

Instead of responding to Allergan's unassailable arguments, Klein-Becker attempts a wholesale rewrite of its complaint. Klein-Becker's changed focus is inappropriate in response to a motion to dismiss, and this Court should grant Allergan's motion to dismiss without leave to amend for several reasons. First, Klein-Becker is simply wrong to argue that no drug company can file for trademark protection for an indication not approved for marketing by the FDA. The Lanham Act, its legislative history, and case law interpreting the Act all contradict Klein-Becker's fabricated rule and instead provide that shipments of a drug for use in clinical trials—trials that must, by federal law, occur prior to FDA's decision whether to approve

the drug for a broad or narrow indication or at all—are sufficient to constitute "use in commerce." Klein-Becker offers no authority to the contrary.

Second, Rule 11 would prevent Klein-Becker from amending its complaint to allege that BOTOX® has not been used in commerce in connection with each and every one of the twelve indications listed on its statement of use. Clinical trials have been ongoing for all uses since at least 1992, and BOTOX® vials have been shipped in commerce in connection with each one. Klein-Becker cannot add to its complaint any allegations that disprove these facts or suggest that the declaration attached to Allergan's trademark application was anything other than the complete truth.

Third, Klein-Becker lacks standing to attack any of the new goods and services listed in Allergan's trademark registration that Klein-Becker now seeks to challenge. Klein-Becker has no basis for arguing that it would be injured by, and thus have standing to challenge, Allergan's trademark registration for the eleven medical indications identified in the trademark registration's statement of use. Moreover, it would be an enormous waste of judicial time and resources to bring into the case at this juncture the evidence, discovery, and motions practice necessary to adjudicate whether Allergan is or is not using BOTOX® in connection with headaches, excessive sweating, facial tremors, and the other indications set forth in its trademark application. Because not one issue in dispute would be furthered toward resolution by opening this case up to Klein-Becker's pointless fishing expeditions into Allergan's other uses of BOTOX®, leave to amend should not be granted.

Klein-Becker's arguments with regard to its preempted false advertising and unfair competition claims are similarly invalid. Klein-Becker's own opposition cites to the Food

Drug & Cosmetic Act ("FDCA") and FDA correspondence invoking the FDCA as authority for its claims against Allergan, thereby demonstrating that resolution of such claims necessarily involves interpretation of the FDCA. Such claims are preempted, as interpretation of the FDCA is within the exclusive jurisdiction of FDA and Congress. Allowing Klein-Becker's claims to go forward would entangle this Court in detailed and potentially conflicting interpretations of FDA's governing statute in a manner specifically prohibited by the Act itself.

Finally, Klein-Becker's previously dismissed state law claim must be dismissed yet again because the claim does not fit into either of the well-accepted elements of Utah unfair competition law. Klein-Becker has alleged neither a palming-off or passing-off claim, nor misappropriation of something of value belonging to it. Klein-Becker's creative arguments to the contrary, previously rejected by this Court, should again be rejected.

II. ARGUMENT

A. Klein-Becker's Trademark-Cancellation Allegations Fail To State A Claim For Fraud On The Trademark Office.

Klein-Becker's meandering opposition boils down to one basic argument: that Allergan did not lawfully use its BOTOX® mark in connection with any of the twelve indications identified in its trademark registration by the time it filed its application in January 2001. Even accepting the SAC's allegations as true for the purposes of this motion, it is beyond doubt that Klein-Becker can prove no set of facts in support of this claim that would entitle it to cancellation of Allergan's trademark registration.

1. The SAC's Trademark Cancellation Claim, As Drafted, Must Be Dismissed Because It Fails To Allege Any Facts That Could Support A Finding Of Fraud On The Trademark Office.

a. Allergan's Statement Of Use Was Completely Truthful Because Allergan Had Used The BOTOX® Mark In Commerce In Connection With "Wrinkles."

The SAC alleges fraud with regard to just one indication in Allergan's trademark registration: wrinkles. Klein-Becker alleges that Allergan "falsely represented . . . that Allergan had used and was using [BOTOX®] to promote a drug for the treatment of 'wrinkles' since as early as 1990, and began using that mark in commerce for the treatment of 'wrinkles' beginning in 1992." SAC ¶ 14. "At that time," Klein-Becker argues, "the FDA did not approve Botox for the treatment of 'wrinkles.'" *Id.* ¶ 15. Because Allergan filed a declaration of use of the mark for wrinkles before FDA had approved the drug for wrinkles, according to the allegations of the SAC, Allergan committed fraud. *Id.* ¶ 17.

Responding to the allegations as made in the SAC, Allergan's motion demonstrated that prior FDA approval and sales of the product are not required for the "use in commerce" prong of the Lanham Act. Rather, "shipments of a new drug to clinical investigators by a company awaiting FDA approval" are sufficient to allege use. Allergan's Motion to Dismiss First, Second, and Third Claims in Klein-Becker usa, LLC's Second Amended Complaint ("Mot.") at 3. Klein-Becker's opposition does not dispute, but rather impliedly admits, that transportation of goods bearing the mark constitutes "use in commerce" under the Lanham Act. Klein-Becker's Memorandum in Opposition to Defendant's Motion to Dismiss the First, Second and Third Causes of Action in Plaintiff's Second Amended Complaint ("Opp.") at 18. Despite this admission, nowhere does the SAC allege that Allergan did not ship BOTOX® vials to investigators for clinical tests on "wrinkles" as Allergan worked toward FDA approval. Indeed, the SAC's allegations support the opposite fact. Allergan received FDA approval for BOTOX® Cosmetic for glabellar lines—or wrinkles between the brow—in 2002, a regulatory decision necessarily preceded by lengthy periods of clinical trials. *See* SAC ¶ 19. Absent allegations that Allergan was not using the mark according to the statutory definition of "use in commerce"—which definition specifically includes shipments for clinical trials—Klein-Becker has failed to allege that Allergan's declaration of use of BOTOX® for "wrinkles" was false.

Klein-Becker makes two arguments in response, both baseless. First, Klein-Becker argues that any use of BOTOX®, even shipments for purposes of conducting clinical trials, prior to FDA approval is unlawful and thus cannot support Allergan's trademark registration. Opp. at 4, 17. This argument displays a fundamental misunderstanding of the FDA approval process. Klein-Becker's ignorance is confirmed by such arguments as "any distinction

between" sales of a good and shipment of goods for clinical trials "is a fabrication" (*id.* at 17) and FDA never approved BOTOX® "for the generalized treatment of wrinkles—whether for sales or clinical testing." *Id.* According to the FDA itself, there is a vital distinction between sales of a good—which may not be marketed until after FDA approval—and shipment of goods for clinical trials. By federal law, clinical testing must occur before FDA approves the drug for marketing. 21 U.S.C. § 301 *et seq*. Thus, shipment of drugs for clinical trials always takes place at a time when the drug is not FDA approved for the indication being studied. Klein-Becker has not alleged any set of facts that would suggest that shipments of BOTOX® vials for use in clinical trials prior to FDA approval violated the FDCA. Klein-Becker's argument, unsupported even by allegations in its own complaint, cannot state a claim against Allergan.

Second, Klein-Becker argues that FDA has never approved BOTOX® for "wrinkles," and thus Allergan has never lawfully used BOTOX® in connection with "wrinkles." Opp. at 17. That is, Klein-Becker argues FDA's approval of BOTOX® Cosmetic for the treatment of glabellar "lines," or "furrows" between the brow, is different than, and exclusive of, an approval for the treatment of "wrinkles." *Id.* This argument relies on the linguistic absurdity that "wrinkles" are different than "lines" or "furrows." Of course, according to the ordinary dictionary definition, Klein-Becker is wrong. Lines and furrows are synonyms of wrinkles. *See generally* The American Heritage Dictionary of the English Language (4th ed. 2000 Houghton Mifflin Co.) (defining "wrinkle" as "A line or crease in the skin, as from age"); WordNet 2.1 (2005 Princeton University) (listing "furrow" and "line" as synonyms for "wrinkle") (attached to Declaration of Mark A. Finkelstein ("Finkelstein Decl.") as Exs. A, B). According to an exhibit to the SAC, even the FDA defined glabellar lines as "furrows, creases, and wrinkles" when it

approved as Allergan's advertising line, "So you can frown, smile, or look surprised—without the furrows, creases, and wrinkles between your eyebrows." SAC Ex. B.

Klein-Becker's SAC itself admits that glabellar lines are wrinkles. The SAC alleges that "FDA has not approved the use of Botox Cosmetic to treat any 'wrinkles,' *other than* deep vertical furrows or 'frown lines' caused by muscle contractions between the eyebrows (generally known as 'glabellar lines') in some, but not all patients." SAC ¶ 30 (emphasis added). Klein-Becker's use of "other than" is an admission of the obvious fact that glabellar lines are one type of wrinkles.[1] Now changing course, Klein-Becker's opposition argues that by using "wrinkles" in its description of goods and services, Allergan committed fraud on the U.S. Patent & Trademark Office ("PTO") because FDA approved BOTOX® Cosmetic for glabellar lines but not for wrinkles. Opp. at 17. Klein-Becker's attempt to draw unsupportable distinctions, which asks this Court to find that lines and furrows are not the same as wrinkles, should be rejected. Because Allergan had shipped BOTOX® product for clinical tests concerning, among many other indications, glabellar lines prior to filing its trademark application, Klein-Becker has failed to allege that Allergan's declaration of use was false.

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[1] By contrast, Klein-Becker's assertion that Allergan has admitted that "lines" are not the same as "wrinkles" (Opp. at 18) mischaracterizes the record. By stating that "StriVectin-SD . . . has not been proven effective to reduce wrinkles or glabellar lines" (Allergan's Opposition to Klein-Becker's Motion for Partial Summary Judgment, at vi), and that Klein-Becker claims effectiveness for "reducing facial fine lines, wrinkles, crow's feet (wrinkles around the eyes), and worry lines—which consumers are likely to equate with glabellar lines" (Allergan's Opposition to Klein-Becker's Motion to Dismiss, or In the Alternative, Summary Adjudication, at 4), Allergan was plainly listing multiple terms for similar concepts—a far cry from admitting that lines are not wrinkles. Indeed, in the same document, Allergan defines glabellar lines as "wrinkles between the brows that form upon frowning." Allergan's Opposition to Klein-Becker's Motion to Dismiss, or In the Alternative, Summary Adjudication, at 4. Klein-Becker's misstatement of the record is contradicted by simple reference to Allergan's actual briefs.

b. Allergan's Statement Of Use Was Completely Truthful Because Allergan's Licensees Had Used The BOTOX® Mark In Commerce In Connection With Many Types Of "Wrinkles."

Even if this Court were to determine that "wrinkles" are different than "lines" or "furrows," Allergan's trademark registration is nevertheless completely truthful because Allergan's licensees use the mark in connection with all different kinds of wrinkles, according to the allegations of the SAC. As Klein-Becker admits, Allergan's customers, the doctors who purchase and prescribe BOTOX®, are lawfully permitted to use BOTOX® for any off-label use, and many doctors do use BOTOX® for several off-label uses including many varieties of wrinkles. SAC ¶ 24; Opp. at 24, Ex. 4. All uses by these doctors, as licensees of the BOTOX® mark, inure to the trademark owner, Allergan. *See* 15 U.S.C. § 1055; *Twentieth Century Fox Film Corp. v. Marvel Enterprises, Inc.*, 220 F. Supp. 2d 289, 293-94 (S.D.N.Y. 2002) (reciting "basic tenet of trademark licensing law, i.e., that . . . any goodwill developed by the licensee through its use of the mark inures solely to the benefit of the licensor"). The SAC alleges that doctors lawfully use the BOTOX® mark in connection with "wrinkles" (SAC ¶ 24), thus defeating Klein-Becker's claim that Allergan, as the owner of the BOTOX® mark, did not possess all rights to the mark for "wrinkles" prior to the filing of its trademark application. Accordingly, Klein-Becker has failed to state a claim for trademark cancellation based on fraud in Allergan's declaration of use.

c. Because The Statement Of Use Was Completely Truthful, Klein-Becker's Argument Regarding The Mental Element Of Fraud Is Wholly Irrelevant.

Klein-Becker spends much of its opposition arguing about the elements of fraud in a cancellation action. *See* Opp. at 5, 8-11. Because the declaration attached to Allergan's

trademark application was completely true, Klein-Becker has failed to allege any facts that show Allergan possessed the state of mind necessary to commit fraud. The BOTOX® mark was in use in commerce for the indications listed on the declaration. According to a known-or-should-have-known standard, an actual-knowledge standard, a sincere-but-unreasonable standard, or any other test of mental state, Allergan made a truthful statement without intent to defraud, according to the allegations in the SAC. Klein-Becker alleges no facts, and none exist, that contradict the statement averred in Allergan's application, and thus Klein-Becker fails sufficiently to allege the requisite mental element for fraud.

2. The SAC Should Be Dismissed Without Leave To Amend Because Klein-Becker Cannot Amend Its Complaint To State A Claim For Fraud.

a. Klein-Becker Wrongfully Attempts To Use Its Opposition Brief To Rewrite The Allegations Of Its Second Amended Complaint.

Instead of addressing Allergan's arguments that demonstrate why the SAC should be dismissed, Klein-Becker attempts by its opposition completely to rewrite its SAC. Whereas the SAC challenges Allergan's dates of first use for "wrinkles" (SAC ¶¶ 15-18), Klein-Becker's opposition changes course and now challenges the "twelve (12) declared uses: 'neurological disorders, muscle dystonias, smooth muscle disorders, autonomic nerve disorders, headaches, wrinkles, hyperhydrosis, sports injuries, cerebral palsy, spasms, tremors, and pain.'" Opp. at 4. By applying for trademark protection for several indications that were not already FDA approved at the date of filing the trademark application, Klein-Becker now argues, Allergan committed fraud on the PTO. Klein-Becker's rewrite is contrary to law on a motion to dismiss.

Other than with respect to "wrinkles," the SAC does not challenge any of these declared uses. By law, Klein-Becker cannot use its opposition brief to change or amend the allegations in its complaint. *See Miller v. Glanz*, 948 F.2d 1562, 1565 (10th Cir. 1991) (in deciding Rule 12(b)(6) motion, federal court may consider only those facts alleged within complaint). Because its complaint challenged only the "wrinkles" portion of Allergan's trademark registration, Klein-Becker's arguments regarding "false description of use" as to the other eleven indications (Opp. at 4) should be rejected outright.

Grasping at straws, Klein-Becker points to phrases within its SAC to supports its new position that it is challenging more than just the "wrinkles" use. But a fraud claim, like the one Klein-Becker seeks to add, must be specific. Fed. R. Civ. P. 9(b).

b. The New Rule Klein-Becker Would Have This Court Adopt—That All Indications Must Be FDA-Approved Verbatim In Order To Be Protected By Trademark—Is Contrary To The Lanham Act.

As drafted, the SAC should be dismissed. And the dismissal should be without leave to amend, because Klein-Becker cannot allege any facts to support its claims. Indeed, the new claims Klein-Becker seeks to bring rely on a fundamental misunderstanding of the FDA approval process and, consequently, the effect of FDA approval of a drug on trademark registrations. According to Klein-Becker, a trademark applicant commits fraud if he declares that a mark has been used in connection with any drug indication that has not *already* received FDA approval at the time of filing of the trademark application. *See* Opp. at 6. Klein-Becker does not cite a single authority for its rule. In fact, this rule would run directly afoul of the legislative history of the Lanham Act itself, as well as decisions interpreting the Act.

As noted above, the legislative history for the Lanham Act contemplates that shipments for clinical trials constitute use for purposes of the Lanham Act's "use in commerce" requirement for registration of a trademark. *See* Mot. at 3, citing Senate Judiciary Committee Report on S. 1883, S. Rep. No. 100-515, at 44-45 (Sept. 15, 1988) *reprinted in* 1988 U.S.C.C.A.N. 5577, 5607; 3 McCarthy, § 19:110. Decisions interpreting the Lanham Act are in accord. *See, e.g., G.D. Searle & Co. v. Nutrapharm, Inc.*, No. 98 Civ. 6890 (TPG), 1999 U.S. Dist. LEXIS 16862, *9-10 (S.D.N.Y. Oct. 29, 1999). By operation of federal law, clinical trials must occur well before FDA approval is granted and, indeed, before the FDA decides or the drug sponsor knows if FDA approval will ever be granted or, if granted, for what indication. *See* 21 U.S.C. § 301 *et seq.*

Accordingly, "unapproved" and "off-label" uses of drugs can, and very commonly do, garner trademark rights for their manufacturers during the long journey toward FDA approval. The PTO's registers are chock full of trademark registrations that do not match up word for word or date for date with the wording and timing of the FDA-approved label for each drug.[2] Klein-Becker's rule, if enacted by this Court, would undermine the validity of each

[2] Recent examples include Crestor® (trademark was registered for "Pharmaceutical preparations for the treatment of cardiovascular diseases for human use only" with first-use date of July 25, 2001, whereas FDA approval for, *inter alia*, "an adjunct to diet to reduce elevated total-C, LDL-C, ApoB, non-HDL-C, and TG levels and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Fredrickson Type IIa and IIb)" was granted on August 12, 2003); Lunesta™ (trademark application for "pharmaceutical preparations, namely analgesics; anti-infective; anti-inflammatories; pharmaceutical preparations for the prevention and treatment of disorders and diseases of the central nervous, peripheral nervous, respiratory and urogenital systems; pharmaceutical preparations for the prevention and treatment of sleep disorders" filed on October 17, 2003, whereas FDA approval for "insomnia" was granted on December 15, 2004; and Meridia® (trademark was registered for "pharmaceutical preparation for the treatment of

of these trademarks and would change the entire scope of the Lanham Act as it applies to the pharmaceutical industry. Plainly, if transportation of goods for clinical tests "by a company awaiting FDA approval" constitutes use in commerce sufficient to form the basis for a trademark registration (*see* Mot. at 3), claiming uses of a mark that arise from the transportation of such goods in connection with indications that are not FDA approved cannot constitute fraud.

Klein-Becker's citation to *Florida Breckenridge, Inc. v. Solvay Pharmaceuticals, Inc.*, 174 F.3d 1227 (11th Cir. 1999), withdrawn, No. 98-4606, 1999 WL 292667 (11th Cir. May 11, 1999) (Opp. at 8) is particularly disingenuous. In *Florida Breckenridge*, counsel for both parties overtly lied to the Court on numerous occasions by insisting that both parties' drugs were exempt from FDA approval altogether. 1999 WL 292667 at *9. The Eleventh Circuit's entire decision centered on the attorneys' misconduct, despite its eventual decision to grant the unopposed motion to dismiss an appeal that was pending before the Court. *Id.* That Court did not issue any decision approaching the rule Klein-Becker seeks to enforce—that trademark rights cannot accrue until FDA approval for the indication set forth in the trademark application has been granted. Klein-Becker's comparison of Allergan's lawful shipment of BOTOX® product in the conduct of its extensive clinical trial program, to the *Florida Breckenridge* parties' deception in open court, is baseless.

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obesity" with first-use date of April 23, 1996, whereas FDA approval for "the management of obesity, including weight loss and maintenance of weight loss, and should be used in conjunction with a reduced calorie diet, . . . recommended for obese patients with an initial body mass index ≥ 30 kg/m^2, or ≥ 27 kg/m^2 in the presence of other risk factors (e.g., diabetes, dyslipidemia, controlled hypertension") was granted on November 22, 1997. Finkelstein Decl. Exs. C-H.

c. Klein-Becker's Complaint Cannot Be Amended To Allege That Use Of The BOTOX® Mark In Connection With Each Of The Twelve Stated Indications Did Not Occur.

Because "simply juxtaposing" Allergan's trademark registration with the indications for which BOTOX® has been FDA-approved (Opp. at 6) is wholly insufficient to allege fraud on the PTO, Klein-Becker also argues that Allergan did not, in fact, ship its BOTOX® product in connection with clinical trials for each of its twelve identified indications. Opp. at 19. Such allegations appear nowhere in the SAC, and Rule 11 would prevent Klein-Becker from amending its complaint to so allege. Although Klein-Becker's come-lately theory surfaced for the first time in its opposition brief, attached to the Finkelstein Declaration submitted herewith is a list of clinical trials for BOTOX® that were ongoing by at least 1990. Finkelstein Decl. Ex. I. While Allergan does not need to rely on these documents in moving to dismiss the SAC as drafted, Allergan supplies them to the Court to demonstrate that the SAC should be dismissed *without* leave to amend.

The list proves that BOTOX® clinical trials testing neurological disorders,[3] muscle dystonias,[4] smooth muscle disorders,[5] autonomic nerve disorders,[6] headaches,[7] sports

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[3] Strabismus (crossed eyes), blepharospasm (eyelid twitching that can lead to blindness), hemifacial spasm (spasms affecting part of the face), spasmodic troticollis (involuntary neck twisting), spastic entropion (inverted eyelid against the eyeball), facial tic (involuntary twitching of facial muscles), nystagmus (involuntary rapid eye movements), lid retraction, levator protective ptosis (drooping of upper eyelid), ormandibular dystonia (lower jaw muscle disorder), limb spasms, larynx and pharynx disorders, and dystonia (disordered muscle tonicity) are all neurological disorders.

[4] Including ormandibular, limb, larynx, pharynx, and general dystonias.

[5] A urinary sphincter is associated with smooth muscle disorders in the lower intestines.

[6] *See supra* n. 2, as well as nerve paralysis.

injuries,[8] cerebral palsy, spasms,[9] tremors,[10] and pain[11] were underway by no later than May 1990. *Id.*; *see also* Allergan's Request for Judicial Notice in Support of its Motion to Dismiss First, Second, and Third Claims in Klein-Becker usa, LLC's Second Amended Complaint ("RJN") Ex. A at 17.[12] FDA's decision to approve BOTOX® for hyperhydrosis in 2004 is further evidence that the drug underwent extensive clinical testing for that indication as well. *Id.* Ex. J.

Additional evidence demonstrates that by 1992, the efficacy of BOTOX® on many of these twelve indications was widely recognized in the professional community, Allergan's consumer base, and the medical literature. *Id.* Ex. K. All of these uses of the BOTOX® mark, regardless of the status of FDA approval for each specific indication, accrued to Allergan, and thus Allergan's trademark registration appropriately included them. 15 U.S.C. § 1055; *Twentieth Century Fox*, 220 F. Supp. 2d at 293-94. Klein-Becker cannot offer a single valid legal argument to the contrary.

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[7] All cranial spasms (including blepharospasm, spastic entropion, facial tic, ormandibular dystonia, hemifacial spasm, and facial tic) involve pain to the head.

[8] Spastic entropion, nerve paralysis, limb spasms, and larynx and pharynx disorders can all occur as a result of sports injuries.

[9] Including blepharospasm, hemifacial spasm, spastic entropion, facial tic, and limb spasms.

[10] *See supra* nn. 3, 7, as well as nystagmus.

[11] *See supra* nn. 7, 9.

[12] Klein-Becker's Opposition provides no justification for this Court to decline to take judicial notice of the documents submitted with Allergan's RJN. Klein-Becker's arguments against this Court's taking judicial notice (Opp. at 18-20) address only the weight of the evidence, not its admissibility in connection with the Motion. Accordingly, Allergan's RJN should be granted in its entirety.

Still more evidence of use was attached to Allergan's trademark application. SAC Ex. A. According to the PTO, Allergan "submitted required color specimen" of use, which was the label attached to each 100-unit packaging of BOTOX® vials. *Id.* Klein-Becker's arguments that no specimen of use was filed with the PTO and that no BOTOX® label was affixed to any drug vial shipped for use in clinical trials (Opp. at 6 n. 2, 19) are contradicted by exhibits attached to its own complaint. Moreover, Klein-Becker's argument that BOTOX® units shipped for double-blind clinical trials do not bear labels when they are shipped (*id.* at 19) is an absurd mischaracterization of the clinical trial process. While the clinicians in double-blind trials do not know whether they are administering BOTOX® or a placebo, they are aware that the trial being conducting is testing BOTOX®, and not an anti-anginal drug or a treatment for athlete's foot. Klein-Becker cannot amend its complaint to allege that BOTOX® was not being used in commerce for each of the eleven medical indications by the early 90s and, to be sure, by the date of Allergan's trademark application in 2001.

d. Klein-Becker Lacks Standing To Challenge The New Eleven Indications, And Permitting It To Do So Would Be A Waste Of Judicial Resources.

Finally, leave to amend should be denied because Klein-Becker lacks standing to launch its purported new challenge against the other eleven indications in Allergan's trademark application (other than wrinkles). Standing to bring a trademark cancellation action, while broad, is not without limits. *Lipton Indus., Inc. v. Ralston Purina Co.*, 670 F.2d 1024, 1028-29 (C.C.P.A. 1982) (holding that in order to have standing to seek to cancel trademark, petitioner must allege facts showing he has personal, real interest in outcome and is not merely intermeddler). As Klein-Becker itself admits, the basis for its challenge of Allergan's BOTOX®

trademark is Allergan's trademark infringement claim against Klein-Becker. Opp. at 14-15 (admitting that standing requires that the party seeking cancellation must be "likely to be damaged by the registration").[13] Of course, Allergan's challenge of Klein-Becker's improper use of Allergan's BOTOX® mark involves only Klein-Becker's own business: its purported anti-wrinkle cream. Klein-Becker could not possibly be damaged by Allergan's registration of its BOTOX® mark for facial spasms, involuntary eye movement, or cerebral palsy. Absent a basis to believe it would be damaged, Klein-Becker is a mere intermeddler and lacks standing to challenge Allergan's trademark registration as to the eleven other indications.

Imposition of the standing requirement here would prevent Klein-Becker from transforming this case into an unreasonably burdensome and irrelevant dispute over Allergan's businesses that have nothing to do with the dispute between the parties. If Klein-Becker's new theory were allowed to proceed, this case would require discovery and trial regarding whether, when, how, and why Allergan transported BOTOX® product for crossed eyes, excessive sweating, drooping of the upper eyelid, neck spasms, and the rest of the medical uses identified in Allergan's trademark application. Klein-Becker is in none of these businesses. It could not possibly be damaged by Allergan's registration for these indications. Accordingly, Klein-Becker has no standing whatsoever to amend its complaint to challenge any of these uses, and leave to amend should not be granted.

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[13] Klein-Becker's supposition about the reasons why Allergan amended its counterclaim (Opp. at 15 n.7) is incorrect, nonsensical, and should be disregarded.

B. The FDCA—FDA's Governing Statute—Preempts Klein-Becker's False Advertising And Unfair Competition Claims.

Klein-Becker's false advertising and unfair competition claims should be dismissed as well because they are preempted by federal law. Klein-Becker admits that the FDCA preempts claims that require the interpretation of the FDCA and its related regulations. Opp. at 26. As Allergan set forth in its motion, Klein-Becker's false advertising and unfair competition claims cannot possibly be adjudicated without direct application and interpretation of the FDCA, including a determination of what constitutes off-label marketing and misbranding under that federal law. Klein-Becker sets up several straw-men claims that it insists this Court can evaluate without application of the FDCA, but each is easily rejected.

First, Klein-Becker argues that its complaint challenges "Allergan's entire illegal marketing campaign," not just Allergan's use of "Cosmetic" as part of the name of its product. Opp. at 22. In fact, the SAC challenges just two of Allergan's ads: the two that were the subject of FDA's letters to Allergan in September 2002 and June 2003. Applying the intricacies of the FDCA, the FDA directed Allergan to change "your toughest wrinkle" to "those tough lines between your eyebrows"; to change "without the furrows, creases, and wrinkles" to "without the furrows, creases, and wrinkles between your eyebrows" (SAC Ex. B) and to remove "most popular cosmetic treatment"—but not "BOTOX® Cosmetic"—from Allergan's advertising. *Id.* Ex. C. Allergan complied with the FDA's directives back in 2002 and 2003, and Klein-Becker does not allege otherwise. Accordingly, the alleged advertising statements that Klein-Becker purports to challenge have not appeared in Allergan's advertising for more than two years and were directly subject to the exercise of FDA's exclusive jurisdiction under the FDCA. Klein-

Becker has failed to allege anything additional that could be false or misleading in Allergan's ads.

The only advertising claim currently made by Allergan that Klein-Becker challenges is Allergan's use of the name "BOTOX® Cosmetic." SAC ¶ 25. There is no dispute that the FDA itself approved that name. *Id.* Second-guessing the FDA is what the preemption provision in the FDCA was design to prevent. *See Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990).

Second, Klein-Becker argues that this Court can adjudicate Klein-Becker's false advertising and unfair competition claims because Allergan fails to police its physician customers and falsified records documenting adverse events in a recent FDA filing. Opp. at 24-25. These allegations do not appear in the SAC. An opposition to a motion to dismiss may not amend the allegations in the complaint being challenged. *Miller*, 948 F.2d at 1565. Accordingly, Klein-Becker's reference to allegations that do not appear in its complaint should not be considered. Moreover, Klein-Becker has cited no authority for its proposition that Allergan can be held liable for "false advertising" purportedly undertaken by physicians.

Third, Klein-Becker cites case authority for the proposition that a court can adjudicate Lanham Act claims against pharmaceutical companies (Opp. at 21-22), but none of the cases it cites supports Klein-Becker. Courts can evaluate ads that promote an off-label drug as a substitute for an approved drug, that claim governmental approval of a drug that has not been approved, or that misrepresent the safety of a drug relative to another approved drug for a particular use. Opp. at 22. Although these cases demonstrate why Klein-Becker's own "Better than Botox®?" advertising is false and misleading, Klein-Becker does not allege in its complaint

that Allergan's advertisements make any of these claims. And not one of these cases provides authority against the FDCA's preemption provision entrusting to the government sole authority to interpret the FDCA and regulations promulgated under the FDCA in situations such as this one.

Klein-Becker's citation to *Upjohn Co. v. Riahom Corp.*, 641 F. Supp. 1209, 1223-24 (D. Del. 1986) (Opp. at 21) provides no support for its claims. In *Upjohn*, the defendant used plaintiff Upjohn's patented drug compound in the defendant's own product and then marketed the product as a cosmetic without conducting any tests as to safety and efficacy or submitting the product to FDA for approval. 641 F. Supp. at 1223. The Court appropriately adjudicated Upjohn's false advertising claim because advertising a product as a cosmetic, which is widely available without a prescription, when it instead is a drug unavailable for lawful sale except by a physician's prescription, can mislead consumers. *Id.* By stark contrast, Allergan does not market BOTOX® Cosmetic as being available without a prescription and has conducted all of the extensive safety and efficacy tests necessary to obtain FDA approval. Klein-Becker does not allege otherwise. Instead, the only "cosmetic"-related portion of Allergan's advertising is its FDA-approved name, BOTOX® Cosmetic. Whether the FDA-approved name is lawful or unlawful is entirely within the scope of the FDA's jurisdiction, and not a question for the courts.

Finally, although Klein-Becker advertises its unapproved wrinkle cream as "Better than Botox®?" by name, Klein-Becker now argues that if consumers are confused by its advertisements into believing that StriVectin-SD is a substitute for BOTOX® Cosmetic, the blame rests with Allergan, and not Klein-Becker, because Allergan uses the FDA-approved name BOTOX® Cosmetic. Opp. at 23. This illogical argument cannot save Klein-Becker's false

advertising and unfair competition claims from preemption. Whether "BOTOX® Cosmetic" is false and misleading and thus misbranded and whether the name suggests approval for off-label uses is uniquely entrusted to the FDA by its enabling statute.

C. Klein-Becker Offers No New Argument Or Law To Support Its Previously Dismissed State Unfair Competition Claim.

Klein-Becker provides only one response to Allergan's motion and this Court's own ruling previously dismissing the very same state unfair competition claim: that Allergan is "passing off" its drug as a cosmetic and "misappropriating" the competitive advantage of cosmetics in general. Opp. at 30. Of course, this is not the definition of passing off or misappropriation under Utah unfair competition law. As this Court already ruled, under long-settled law, a claim for state unfair competition must allege one of two unfair acts: a party has attempted to pass off another party's product as its own or palm off its own product as another party's, or a party has misappropriated for its own benefit something of value belonging to another party. *See* Mot. at 13-14. Klein-Becker's claim, which alleges neither of these acts, should again be dismissed.

III. CONCLUSION

Klein-Becker provides no valid response to any of Allergan's arguments for dismissal of the SAC's first three claims. For the foregoing reasons, Allergan respectfully requests that its motion to dismiss be granted in its entirety, and that leave to amend be denied.

Dated this 28th day of November, 2005.

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CERTIFICATE OF SERVICE

I hereby certify that I caused to be served a true and accurate copy of the foregoing **DEFENDANT ALLERGAN, INC.'S REPLY IN SUPPORT OF MOTION TO DISMISS THE FIRST, SECOND AND THIRD CAUSES OF ACTION IN PLAINTIFF'S SECOND AMENDED COMPLAINT**, which was sent via electronic mail and first-class mail, on the 28th day of November, 2005:

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